DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 26, 2014

Topcon Corp.
% Ms. Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864 US

Re: K133667
Trade/Device Name: Slit Lamp SL-D701
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slit Lamp Biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: July 10, 2014
Received: July 11, 2014

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133667

Device Name
Slit Lamp SL-D701

Indications for Use *(Describe)*
The Slit Lamp SL-D701 is an AC-powered slitlamp biomicroscope intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) SUMMARY

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Slit Lamp SL-D701

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Date Prepared: August 22, 2014

Trade Name of Device
Slit Lamp SL-D701

Common or Usual Name
AC- Powered Slit-Lamp Biomicroscope

Classification Name
AC-powered slitlamp biomicroscope; 21 C.F.R. 886.1850
Class II
Product Code: HJO

Predicate Devices
Haag-Streit AG Slit Lamp BM 900, BQ 900, BP 900 (K100202)
TOPCON CORPORATION Slit Lamp SL-2G (K110489)

Device Description
The Slit Lamp SL-D701 is an AC-powered device that is a microscope intended for use in eye examination that projects into a patient's eye through a control

diaphragm a thin, intense beam of light. The Slit Lamp SL-D701 is composed of the following components: microscope unit, illumination unit, base unit, chinrest, table and power unit. The slitlamp biomicroscope is used for the observation of the eye. It has an illumination unit to illuminate the eye, and a binocular stereoscopic microscope to zoom and observe patient's eyes, and also can observe the three-dimensional image.

Intended Use / Indications for Use
The Slit Lamp SL-D701 is an AC-powered slitlamp biomicroscope intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

Substantial Equivalence
The Topcon Slit Lamp SL-D701 is substantially equivalent to the predicate devices, the HAAG-STREIT Slit Lamps BM 900/BQ 900/BP 900 (K100202) and the TOPCON CORPORATION Slit Lamp SL-2G (K110489).

The indications for use statement for the Slit Lamp SL-D701 is exactly the same as the Haag Streit Slit Lamp BM 900/BQ 900/BP 900 (K100202) and the Topcon SL-2G (K110489) indications for use statement. Additionally, the Slit Lamp SL-D701 and the predicate devices are all prescription devices used by trained professionals. The intended use for the Slit Lamp SL-D701 and the identified predicate devices is to examine the anterior eye segment for diagnostic purposes. Therefore, the Slit Lamp SL-D701 may be found to be substantially equivalent to the predicate devices.

The Topcon Slit Lamp SL-D701 has similar technological characteristics to the predicate devices. The Slit Lamp SL-D701 and the predicate devices are all AC-powered slit lamp biomicroscopes that project a beam of light into the patient's eye through a control diaphragm. Exposure parameters including slit image width, slit image length, illumination field diameter and slit direction are all within the specifications of the previously cleared predicate devices. The slit image width is 0-14 mm in the Slit Lamp SL-D701 which is the same as the slit image width in the SL-2G. The slit image length is 0-14 mm in the Slit Lamp SL-D701 which is the same as the slit image width in the SL-2G.

The light source (illumination/observation) for the Slit Lamp SL-D701 is an LED, which is a similar light source for the SL-2G and one of the available light sources for the BM 900/BQ 900/BP 900 series of slit lamps. In the Topcon Slit Lamp SL-D701 the maximum brightness setting of the illumination/observation LED is at 440,000 Lux, which is equivalent to the setting of the LED used in Haag Streit slit lamps. Both the Topcon Slit Lamp SL-D701 and the Haag-Streit

have the same magnification steps (difference between 6x and 6.3x is negligible) and eyepiece lens magnification.

All slit lamps, the Topcon Slit Lamp SL-D701, the Topcon Slit Lamp SL-2G cleared in K110489, and the Haag-Streit slit lamp cleared in K100202 comply with the following consensus standards: IEC 60601-1, IEC60601-1-2, ISO 15004-2:2007 and ISO 10939:2007.

The Slit Lamp SL-D701 has the same intended use and indications for use, technological characteristics, and principles of operation as the previously cleared predicates.

Performance Data

The following bench testing was conducted in order to support substantial equivalence:

- ISO 15004-1:2006 Ophthalmic instruments – Fundamental requirements and test methods – Part 1: General requirements applicable to all ophthalmic instruments. The testing found that the product met the requirements of ISO 15004-1:2006.
- ISO 15004-2:2007 Ophthalmic Instruments – Fundamental requirements and test methods – Part 2: Light hazard protection. The testing found that the device is a Group 2 instrument which is non-hazardous.
- ISO 10939:2007 Ophthalmic Instruments – Slit-lamp microscopes found that the SL-D701 complies with the requirements of the standard.